CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203858Orig1s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	December 12, 2012
Reviewer:	Sarah K. Vee, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Yelena Maslov, PharmD Division of Medication Error Prevention and Analysis
Division Director:	Carol A. Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Juxtapid (Lomitapide) Capsules, 5 mg, 10 mg, and 20 mg
Application Type/Number:	NDA 203858
Applicant/Sponsor:	Aegerion Pharmaceuticals
OSE RCM #:	2012-2717

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Juxtapid, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

NDA 203858 for Lomitapide was submitted on February 29, 2012. The primary proprietary name, (b) (4) was found unacceptable in OSE Review #2012-556 dated, May 29, 2012. Subsequently, the Applicant submitted an alternate proprietary name, (b) (4) (b) (4) which OPDP found unacceptable (b) (4). A third name, was evaluated and found unacceptable in OSE Review #2012-1836 dated, October 25, 2012.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 28, 2012 proprietary name submission.

- Active Ingredient: Lomitapide mesylate
- Indication of Use: A microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering drugs with or without LDL apheresis to reduce low-density lipoprotein cholesterol, total cholesterol, apolipoprotein B and triglycerides in patients with homozygous familial hypercholesterolemia
- Route of Administration: Oral
- Dosage Form: Capsules
- Strength: 5 mg, 10 mg, 20 mg
- Dose and Frequency: The recommended starting dose is 5 mg. After 2 weeks the dose may be increased, based on acceptable safety and tolerability, to 10 mg and then, at a minimum of 4-week intervals, to 20 mg, 40 mg, and the maximum recommended dose of 60 mg. Administered once daily at bedtime, with a glass of water and without food.
- How Supplied: Bottles of 28 capsules
- Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. Keep container tightly closed and protect from moisture.
- Container and Closure Systems: 100 mL HDPE bottles with child resistant closure

The Applicant proposes REMS program for this product in order to:

- Ensure that healthcare providers (HCPs) understand the appropriate use of this drug within the indicated population (patients with homozygous familial hypercholesterolemia (HoFH)).
- Minimize the serious risks of hepatotoxicity and teratogenicity that may be associated with this drug.
- Inform HCPs and patients about the serious risks associated with the use of this product.

The proposed REMS program includes the following components:

- Medication Guide
- A Dear Healthcare Provider (HCP) Letter
- A Dear Professional Society Letter
- Elements To Assure Safe Use:
    - Healthcare Providers who prescribe Juxtapid are specially certified.
    - Juxtapid will be dispensed only by a limited number of specialty pharmacy providers that agree to follow the REMS requirements.
    - Juxtapid will be dispensed only to patients with evidence or other documentation of safe-use conditions.

2. RESULTS

The following sections provide the information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolic and Endocrinology Products (DMEP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

The November 28, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Juxtapid, does not have any derivation or an intended meaning. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

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